K050826

Appendix A

APR 1 0 2006

Section E - 510 K Summary

Applicant Information

Applicant Information:

Cetro America, Inc.
925 Sherman Avenue
Hamden, CT 06514
Phone: (203) 248-0500
Fax: (203) 288-9032
E-mail: admin@cetroamerica.com

Establishment Registration Number: 3004167720

Contact Information:

Maya Cianciolo
Cetro America
925 Sherman Avenue
Hamden, CT 06514
Phone: (203) 248-0500
Fax: (203) 288-9032
E-mail: admin@cetroamerica.com

Date Prepared: March 14, 2005

Device Name

Device Trade Name:

Cetro America Replacement Device Trade Name	OEM Equivalent Device Name
TOCO Transducer Model 8032009-04	HP Toco 1355A for 1350+ Series and more recent model monitors
ULTRASONIC Transducer Model 8031012-02	HP Ultrasound 1356 A for 1350 Series Monitor
TOCO Transducer Model 8032010-04	Corometrics Toco for all model monitors
TOCO Transducer Model 8032007-04	AMS/Spacelabs TD84 for FM Model IM76 and AM 66
ULTRASONIC Transducer Model 8031010-02	AMS/Spacelabs US91 for FM Model IM76 and AM 66
TOCO Transducer Model 8032008-04	AMS/Spacelabs TD84 for FM Model IM77 and AM 67
ULTRASONIC Transducer Model 8031011-02	AMS/Spacelabs US915 for FM Model IM77 and AM 67

Device Common Name: Transducers for Ultrasonic and Tocodynamometer fetal monitoring

Device Classification: Class II (performance standards)
Regulation Description: Perinatal monitoring system and accessories.

Regulation Numbers: 21 CFR 884.2740
Product Codes: 85 HGM

Predicate Device

Predicate Device: These devices are equivalent to the following legally marketed devices:

- *Corometrics 174* (U/S 5700 and TOCO 2260) K891595
- *Corometrics* 145 K852076
- *HP 1356* (U/S 1356A and TOCO 1355A) K900480
- *AMS IM-76* (U/S US91 and TOCO TD84) K852518
- *AMS IM-77* (U/S US915 and TOCO TD84) K940898

Device Description

Cetro America, Inc. Transducers for Ultrasonic and Tocodynamometer fetal monitoring will be used as replacements for similar transducers manufactured by Corometrics (currently GE), Hewlett Packard Medical (currently Phillips Medical) and Advanced Medical Systems (currently Spacelabs Medical) and their respective fetal monitors. The ultrasound transducer is used to detect Fetal Heart Rate (FHR) using the ultrasound Doppler shift technology. Ultrasound transducers operate in a pulsed Doppler mode with around a 33% Duty Cycle. The Tocodynamometer transducer uses a strain gauge to detect uterine contraction frequency and duration during labor.

Intended Use

These devices are replacement accessories for the original manufacturer's fetal monitor transducers and are intended to monitor and chart Fetal Heart Rate and maternal uterine activity.

Predicate Comparison (Substantial Equivalence)

Category	Cetro America	Coro 174	Coro 145	HP 1356	AMS IM-76	AMS IM-77
Intended Use (Ultrasound)	To detect, measure and record fetal heart rate and the duration and frequency of uterine contractions during labor.	Same	Same	Same	Same	Same
Intended Use (Toco)	To detect, measure and record uterine pressure to determine timing of contractions.	Same	Same	Same	Same	Same
Target Patient Population	Gravid patients, particularly during labor.	Same	Same	Same	Same	Same
Anatomical sites	The ultrasound transducer is placed on the patient's abdomen aimed at the fetal heartbeat. The Toco is placed on the patient's abdomen at the top of the uterus.	Same	Same	Same	Same	Same
FHR Range	As to monitor system specifications	Same	Same	Same	Same	Same
Uterine Activity Range	As to monitor system specifications	Same	Same	Same	Same	Same
Patient	Reusable	Same	Same	Same	Same	Same

Use/Reuse						
Sterility	Non-sterile	Same	Same	Same	Same	Same
Patient Attachment	These devices attach to the patient with elastic belts strapped to the patient	Same	Same	Same	Same	Same
Cable Length	Eight feet	Same	Same	Same	Same	Same
Accessories	Transducer belts and Ultrasonic Gel	Same	Same	Same	Same	Same
Connector Design	Transducers are color coded and designed to fit into the appropriate monitoring system.	Same	Same	Same	Same	Same
Acoustic Output (Ultrasound Transducer)	<20mW/cm2 average	Same	Same	Same	Same	Same

Category	Cetro America	Coro 174	Coro 145	HP 1356	AMS IM-76	AMS IM-77
Operational Characteristics	Cetro 8031010-02 – Pulsed Doppler	--	--	--	Same	--
	Cetro 8031011-02 – Pulsed Doppler	--	--	--	--	Same
	Cetro 8031012-02 – Pulsed Doppler	--	--	Same	--	--
Specifications (U/S Center Frequency)	Cetro 8031010-02 – 1.536 MHz	--	--	--	Same	--
	Cetro 8031011-02 – 1.024 MHz	--	--	--	--	Same
	Cetro 8031012-02 – 0.9984 MHz	--	--	Same	--	--

Conclusion:
Bench testing demonstrates that the devices perform as intended.

The company declares conformity to consensus performance standards relating to Electrical/Mechanical/Thermal Safety and Biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 10 2006

Ms. Maya Cianciolo
Official Correspondent
Cetro America
9025 Sherman Avenue
HAMDEN CT 06514

Re: K050826
Trade Name: Transducers for Ultrasonic and Tocodynamometer Fetal Monitor
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: March 22, 2006
Received: March 22, 2006

Dear Ms. Cianciolo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Transducers for Ultrasonic & Tocodynamometer Fetal Monitoring, as described in your premarket notification:

Transducer Model Number

TOCO Transducer Model 8032009-04
ULTRASONIC Transducer Model 8031012-02
TOCO Transducer Model 8032010-04
TOCO Transducer Model 8032007-04
ULTRASONIC Transducer Model 8031010-02
TOCO Transducer Model 8032008-04
ULTRASONIC Transducer Model 8031011-02

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Ms. Michelle Byrne at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures

Section D - Indications for Use

Device Name: Cetro America...

TOCO Transducer Model 8032009-04
ULTRASONIC Transducer Model 8031012-02
TOCO Transducer Model 8032010-04
TOCO Transducer Model 8032007-04
ULTRASONIC Transducer Model 8031010-02
TOCO Transducer Model 8032008-04
ULTRASONIC Transducer Model 8031011-02

Indications for Use: These devices are replacement accessories for the original manufacturer's fetal monitor transducers and are intended to obtain signals to monitor and chart Fetal Heart Rate and maternal uterine activity on a fetal monitor. Please refer to the chart below for appropriate replacement pairings:

Cetro America Replacement Device Name	OEM Equivalent Device Name
TOCO Transducer Model 8032009-04	HP Toco 1355A for 1350+ Series and more recent model monitors
ULTRASONIC Transducer Model 8031012-02	HP Ultrasound 1356 A for 1350 Series Monitor
TOCO Transducer Model 8032010-04	Corometrics Toco for all model monitors
TOCO Transducer Model 8032007-04	AMS/Spacelabs TD84 for FM Model IM76 and AM 66
ULTRASONIC Transducer Model 8031010-02	AMS/Spacelabs US91 for FM Model IM76 and AM 66
TOCO Transducer Model 8032008-04	AMS/Spacelabs TD84 for FM Model IM77 and AM 67
ULTRASONIC Transducer Model 8031011-02	AMS/Spacelabs US915 for FM Model IM77 and AM 67

David A Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050826

Prescription Use ✓